

**Ethics reference:** 2024 FULL 15231

5 April 2024

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Tēnā koe Dr Shaikh

### **APPROVAL OF APPLICATION**

Study title: The NEOgrads playgroup study: Improving developmental motor outcomes through intensive Early Intervention in preterm infants: A feasibility study.

I am pleased to advise that your application was **approved** by the Northern A Health and Disability Ethics Committee (the Committee). This decision was made through the FULL pathway.

### **Conditions of HDEC approval**

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern A Health and Disability Ethics Committee is required.

Standard conditions:

- Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
- Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a registry approved by the World Health Organization (such as the Australia New Zealand Clinical Trials Registry, [www.anzctr.org.au](http://www.anzctr.org.au) or <https://clinicaltrials.gov/>).
- Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Ethics RM. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

### **After HDEC review**

Please refer to the [SOPs](#) for HDEC requirements relating to amendments and other post-approval processes.

**Your next progress report is due by 05 April 2025.**

### **Participant access to compensation**

The Northern A Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialed. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation.

### **Further information and assistance**

Please contact the HDECs Secretariat at [hdec@health.govt.nz](mailto:hdec@health.govt.nz) or visit our website at [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz) for more information, as well as our [General FAQ](#) and [Ethics RM user manual](#).

Nāku noa, nā



Ms Catherine Garvey

Chair

Northern A Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix B: statement of compliance and list of members

**Appendix A: Documents submitted**

| Document Type                    | File Name   | Date       | Version |
|----------------------------------|---|------------|---------|
| CV for Coordinating Investigator | N Shaikh CV - generated 2024-02-29 10-29                                |            |         |
| Response to PA Document          | NEOgrads home visit safety screening V1.1                               |            | 1.1     |
| Response to PA Document          | NEOgrads class training manual V1.2                                     |            | 1.2     |
| Response to PA Document          | Clean Copy NEOgrads data management plan V1.3                           |            | 1.3     |
| Response to PA Document          | NEOgrads data management plan V1.3                                      |            | 1.3     |
| Response to PA Document          | Clean Copy NEOgrads Research protocol V1.6                              |            | 1.6     |
| Response to PA Document          | Tracked changes NEOgrads Research protocol V1.6                         |            | 1.6     |
| Response to PA Document          | Tracked changes NEOgrads Participant information sheet Parent V1.5      |            | 1.5     |
| Response to PA Document          | Clean Copy NEOgrads Participant information sheet Parent V1.6           |            | 1.6     |
| Response to PA Document          | Tracked changes NEOgrads Participant information sheet Assent V1.3      |            | 1.3     |
| Response to PA Document          | Clean Copy NEOgrads Participant information sheet Assent V1.3           |            | 1.3     |
| Response to PA Document          | HDEC reponse letter LP  |            |         |
| Evidence of Consultation         | MMC 2023 consultation feedback _ Pearce (2)                             | 04/09/2023 | 1       |
| Scientific Peer Review           | HES PGR1 MHS <sub>c</sub> 120pts PEARCE Louise 9901565 Oct 2023 (FINAL) | 18/10/2023 | 1       |
| Scientific Peer Review           | hdec-peer-review_MackeyOct23  | 24/10/2023 | 1       |
| Protocol                         | Neograds Research protocol V1.4   | 12/11/2023 | 1.4     |
| PIS/CF                           | NEOgrads Participant information sheet Parent V1.3                      | 12/11/2023 | 1.3     |
| Advertisement                    | NEOgrads study poster V1.1  | 21/11/2023 | V1.1    |
| Data Management Plan             | Data management plan V1.1 NEOgrads                                      | 21/11/2023 | 1.1     |
| Surveys/questionnaires           | NEOgrads Parent Caregiver Survey V1.1                                   | 21/11/2023 | 1.1     |
| Assent form                      | NEOgrads Participant information sheet Assent V1.3                      | 21/11/2023 | 1.3     |
| Other                            | Data management plan V1.1 NEOgrads                                      | 21/11/2023 | 1.1     |
| Response to PA Document          | NEOgrads home program logbook V1.1                                      | 21/11/2023 | 1.1     |
| Response to PA Document          | NEOgrads home visit safety plan V1.1                                    | 16/02/2024 | 1.1     |

## **Appendix B: Statement of compliance and list of members**

### Statement of compliance

The Northern A Health and Disability Ethics Committee

- is constituted in accordance with its Terms of Reference
- operates in accordance with the [Standard Operating Procedures for Health and Disability Ethics Committees](#), and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

### List of members

Ms Catherine Garvey (Lay (the law)), Dr Kate Parker (Non-lay (observational studies)), Dr Sotera Catapang (Non-lay (observational studies)), Mr Johnathan Darby (Lay (the law/ethical reasoning)), Ms Jade Scott (Non-lay (observational/intervention studies)), Dr Andrea Forde (Non-lay (intervention studies)), Mr Derek Chang (Non-lay (intervention studies)).

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference).

<http://www.ethics.health.govt.nz>